In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-1038V UNPUBLISHED

JENNIFER ARNOLD.

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 9, 2021

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On August 19, 2020, Jennifer Arnold filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury, after receiving a tetanus, diphtheria,

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

acellular pertussis ("Tdap") vaccine³ on May 2, 2019. Petition at 1, ¶¶ 2, 7. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find the Tdap vaccine was most likely administered in Petitioner's left deltoid, as alleged.

I. Relevant Procedural History

Along with the petition, Ms. Arnold filed the affidavit and medical records required under the Vaccine Act. Exhibits 1-5, ECF No. 1; see Section 11 (c). On November 17, 2020, Respondent filed a status report indicating the Health & Human Services ("HHS") review would not be completed for at least six months. Status Report at 2, ECF No. 13. Respondent also noted that the record indicated Petitioner received two vaccines on May 2, 2019 – but both administered in her right arm.⁴ Status Report at 1.

On January 28, 2021, Petitioner filed unsworn declarations⁵ from herself and her husband, which included copies of emails she sent to the vaccine administrator (Rite Aid Pharmacy) in December 2020 regarding the discrepancy between the vaccine record and Petitioner's assertion that she received one vaccine in each arm. Exhibits 6-7, ECF No. 14. On April 22, 2021, she filed a motion for a factual finding regarding the site of vaccination. ECF No. 18. During email correspondence, Respondent confirmed that he did not wish to file a response to Petitioner's motion. See Informal Remarks, dated Apr. 22 and May 5, 2021. The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the Tdap vaccination alleged as causal in her injured left deltoid, rather than her right deltoid as the vaccine documentation indicates.

³ Petitioner also received a Hepatitis B ("Hep B") vaccine – which, like the Tdap, is also the basis for a SIRVA Table claim. 42 C.F.R. § 100.3(a)(I)(C), (II)(C), VIII(B) (2017) (most recent Vaccine Injury Table for SIRVA following receipt of a Tdap or Hep B vaccine). However, as discussed below, my finding that only the Tdap vaccine was likely administered in her left arm means that she cannot proceed with a claim based on the Hep B vaccine.

⁴ In the status report, Respondent also indicated there was no factual issue which required further development while awaiting HHS review. Status Report at 2. However, it appears this later language, seen often in the status report from Respondent's counsel, may have mistakenly been included.

⁵ Although not notarized, the declarations are signed under penalty of perjury. Exhibits 6-7; see 28 U.S.C. § 1746 (regarding the weight of unsworn declarations if signed under penalty of perjury).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the finding regarding site of vaccination after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I base the findings on the following evidence:

- The vaccine record indicates Petitioner received the Tdap vaccine she maintains caused her SIRVA, along with the Hep B vaccine, in her *right* upper arm on May 2, 2019. Exhibit 1. It also indicates she previously received influenza and Hep B vaccines in her upper left arm on January 29, 2016. *Id.*
- In her declaration, Petitioner alleges that she in fact received one vaccine in each arm on May 2nd – the Tdap vaccine in her left injured arm, and the Hep B vaccine in her right arm. Exhibit 6 at 1.
- Petitioner's husband did not witness the vaccinations, but stated in his declaration that he recalls Petitioner applying ice and heat to her left shoulder within 24 hours of vaccination to treat her shoulder pain. Exhibit 7.
- On May 25, 2021, 23 days post-vaccination, Petitioner sought treatment from her primary care provider ("PCP") during an urgent care appointment. Exhibit 2 at 54-57. Indicating she had experienced the left shoulder pain since receiving vaccines⁶ at Rite Aid Pharmacy on May 2, 2019, Petitioner described it as moderate and sharp pain which traveled down her arm. *Id.* at 54. Upon examination, she exhibited reduced range of motion ("ROM"). Diagnosed with subacromial bursitis, she declined a cortisone injection and was prescribed home exercises. *Id.* at 56.

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⁶ In the same paragraph, the vaccines Petitioner received were listed as the HPV (human papillomavirus) and Tdap vaccines and the Hib (Haemophilus influenzae type b) and Tdap vaccines. Exhibit 2 at 54.

- In her declaration, Petitioner indicated that she obtained her vaccine record at Rite Aid Pharmacy after her appointment on May 25, 2019, but did not notice the error in the vaccine record, regarding site of vaccination for the Tdap vaccine, until she arrived home. Exhibit 6. She called the pharmacy and was told they could not correct the record. *Id.* at 1.
- On August 16, 2019, Petitioner returned to her PCP complaining of continued left shoulder pain, now at a level of nine out of ten. Exhibit 2 at 50. The severity of her limited ROM had also increased. Petitioner again attributed her left shoulder pain to the Tdap vaccine she received, indicating the pain "started 3 months ago, immediately after getting her Tdap injection." *Id.* She was prescribed muscle relaxers and told to continue icing her arm. *Id.* at 52.
- The record from her physical therapy ("PT") evaluation, performed on September 30, 2019, indicates Petitioner "report[ed] having 2 immunizations in [her] left shoulder in May, and state[d] [her] shoulder stiffened up after this and 'never went away." Exhibit 2 at 43. It was recommended that Petitioner undergo twice weekly PT for six weeks. *Id.* at 42.
- In her declaration, Petitioner included snapshots of written correspondence with Rite Aid Pharmacy on their website portal, requesting a correction of the vaccine record. Exhibit 6 at 2. She was told to contact the local pharmacy where she received the vaccinations. *Id.*

The above medical entries show that, when seeking treatment for her left shoulder pain, Petitioner consistently attributed her pain to the vaccine she reported receiving in her left arm. She provided these histories to her PCP and physical therapist soon after vaccination, from several weeks through almost five months post-vaccination. While originating from Petitioner, these statements are set forth in contemporaneous records, and should therefore be afforded greater weight than any subsequent assertion or witness statement. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this class of information, even when the record in question simply memorializes what the petitioner said at the time.

Respondent correctly observes that the medical history contained in Petitioner's September 30, 2019 initial PT evaluation, performed almost five months post-vaccination,

indicating that *both* vaccines were administered in her left arm. Status Report at 1 (citing Exhibit 2 at 46). Additionally, the medical record from Petitioner's urgent care appointment on May 26, 2019, erroneously identifies the other vaccine administered on May 2nd, in addition to the Tdap vaccine, as the HPV and Hib vaccines. These errors, however, do not detract from the primary message conveyed by Petitioner - that she was vaccinated in her left injured arm. I thus find they do not reduce the probative value of the information regarding site of vaccination.

The only evidence supporting a finding that the vaccination was administered in Petitioner's right (opposite) arm is the entry from the administration record provided by Rite Aid Pharmacy. But based upon my experience resolving SPU SIRVA cases (approximately 700 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled in chambers, I find it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect. Many of these systems use a "dropdown" menu which may not be updated each time a separate vaccine is administered to a different individual. See, e.g., Mezzacapo v. Sec'y of Health & Human Servs., No. 18-1977V, 2021 WL 1940435, at *6 (Fed. Cl. Spec. Mstr. Apr. 19, 2021) 7; Desai v. Sec'y of Health & Human Servs., No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Human Servs., No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Human Servs., No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply because they come first – and in fact the nature of their creation provides some basis for not accepting them at face value.

Furthermore, Petitioner's assertion that she received the two vaccines, one in each arm, in both 2019 and 2016, despite what is shown in the vaccine record, is realistic and credible. In numerous cases involving the administration of multiple vaccinations at the same time, the practice of administrators has been to administer the vaccines in both arms. *E.g.*, *Rodgers*, 2020 WL 1870268, at *5.

There is a dearth of evidence to support the determination that both vaccines were administered in Petitioner's right arm – while sufficient other reliable evidence supports Petitioner's assertion. I thus determine, based on the record as a whole, that

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⁷ In this ruling by one of my special master colleagues, the pharmacist who had administered the relevant vaccination testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, because most vaccinees are right-handed. The pharmacist's testimony was deemed credible, and the site of vaccination found to be as the petitioner alleged, rather than what was indicated in the vaccine record.

preponderant evidence establishes that the Tdap vaccine to which Petitioner attributes her SIRVA was most likely administered in her left deltoid on May 2, 2019.

V. Scheduling Order

Based on recent data, I expect the HHS review to be completed in this case in August or September 2021. Although not clear whether Petitioner's injury meets all criteria for a Table SIRVA, given my finding of fact with regard to the site of vaccination, it appropriate for Petitioner to forward a demand and supporting documentation to Respondent prior to the HHS review. Thereafter, Respondent's counsel should indicate, at a minimum, if additional documentation is needed to support Petitioner's demand.

Petitioner shall file a status report updating me on her demand by no later than <u>Tuesday</u>, <u>July 27</u>, <u>2021</u>. The status report shall indicate the date by which Petitioner provided, or intends to provide, a demand and supporting documentation to Respondent. Additionally, Petitioner shall confirm whether any Medicaid lien exists, and if so, indicate the date by which Petitioner anticipates providing Respondent a letter from the appropriate state agency verifying the amount of the lien.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master